REMARKS/ARGUMENTS

In the Claims:

Claims 1-39, 46-49, 65-69 and 80-82 remain pending in the present application. Claims 1, 31, 46 and 65 have been amended to more clearly describe the subject matter recited therein. Claims 40-45, 50-64, 70-79, and 83-85 have been withdrawn by the Examiner as a result of a previous restriction requirement.

Rejection of Claims 31-37, 39, 46-48, 65-67 and 82 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e) as being anticipated by Clynch (US 6,463,351). As Applicant does not believe Clynch to teach the subject matter of claims 31-37, 39, 46-48, 65-67 and 82, the rejection is respectfully traversed.

The system and method of the present invention allows for the automatic configuration of one or more acceptable medical devices based on at least one patient attribute and/or various other criteria. Patient information can be gathered and stored such that the patient information can be used as criteria for selecting the most appropriate individual medical device components for use in assembling the overall medical device. Based on the selection criteria, the system and method of the present invention can provide several medical device options from which a patient or practitioner can select. The selection criteria,

optionally along with other criteria, may be used to rank the several medical devices.

The system and method of the present invention is a leap forward with respect to the system and method generally used to configure such medical devices, wherein a practitioner is required to wade through a multitude of possible choices for each of the plurality of components from which a medical device may typically be constructed. (See, for example, paragraphs [0002]-[0008] of present application). Rather, by providing the system of the present invention with certain selection criteria (e.g., at least one patient attribute), the system is able to automatically scan through a potentially vast array of available medical device components in order to create one or more potentially acceptable medical devices. For example, an exemplary lower body prosthesis configured by the system and method of the present invention may include individual components comprising at least a foot, ankle, shin, knee, socket interface, suspension device, connector(s), and cosmetic covering. (See paragraph [0003] of present application). When it is realized that there may be dozens of choices with respect to each such component, the benefit of the present invention can be easily understood.

Contrary to the Examiner's assertion, Clynch does not teach the subject matter of the rejected claims. For example, the Examiner asserts that Clynch (at col. 4, ll. 49-53 and col. 7, line 61–col. 8, line 10) teaches a means for and/or populating a digital repository with information corresponding to a plurality of

medical device components. However, upon review, it will be understood that these sections of Clynch do not support the Examiner's assertions. The first section of Clynch referred to by the Examiner teaches only that a scan facility to which a prosthetic model is sent is equipped with equipment capable of scanning and capturing a three-dimensional image of a target surface and for converting the image into a digitized data file. There is no mention of a digital repository or any medical device components. Similarly, the second section of Clynch referred to by the Examiner is devoid of such disclosure. Rather, this portion of Clynch teaches only that certain predefined modifications may be available via the CAD application used to manipulate a digital body part model. (See col. 7, ll. 14-52). While these predefined modifications may be stored in a database, they are *not* medical device components – they are simply prosthetic device *modifications* that can be selected to account for particular characteristics of a body part. (See col. 7, ll. 45-52 for specific modification examples). Consequently, neither of the sections of Clynch cited by the Examiner teach populating a digital repository with information corresponding to a plurality of *medical device components*.

The cited section (col. 5, ll. 1-6) of Clynch also does not teach interviewing a patient having a need for a medical device to determine at least one patient attribute. Rather, this section of Clynch simply teaches that a patient visits a clinic where a physician makes a model (cast) of a patient's body part. There is no suggestion that the patient is interviewed so that patient characteristics, needs or desires (i.e., at least one patient attribute) can be subsequently used to select,

adjust, manipulate, or otherwise affect the produced medical device. This is an important distinction, as the system and method of the present invention allows for a medical device to be configured to meet one or more specific needs or desires of a patient (i.e., the digital repository is queried for a subset of medical device components based on at least one patient attribute). Thus, the patient's input can directly affect the manner in which the medical device is configured. For example, if a patient desires a prosthetic limb that is as light as possible, the system and method of the present invention can use weight as the main criteria for sorting through the various components that could otherwise be used to construct an acceptable prosthesis. No such option is taught by Clynch. Nor, as is also asserted by the Examiner, is there a teaching at the cited sections of Clynch for storing at least one such patient attribute. Rather, all that is taught at these latter sections of Clynch is that multiple scanning facilities and physician's clinics may be in communication with one another.

Further, as Clynch does not teach populating a digital repository with information corresponding to a plurality of medical device components or interviewing a patient having a need for a medical device to determine at least one patient attribute, Clynch cannot teach querying a digital repository for a subset of medical device components based on the at least one patient attribute. As discussed above, the sections cited by the Examiner in support of this assertion are directed to the display and manipulation of a digital model of a patient's body part using specialized CAD software. Operation of the CAD

application has nothing to do with querying for or selecting medical device components. It is used only to manipulate the size and/or shape of the digital model so that a resulting prosthetic device based thereon will best fit the patient. The only data that may be accessed in this regard is data relating to specific predefined modifications that may be applied to the model. That is, modifications that may be made to the size and/or shape of the model. No medical device components are involved.

The primary difference between Clynch and the present invention is that Clynch is directed to optimizing the fit of a simplistic *single component* medical device, such as a prosthetic socket, whereas the system and method of the present invention is directed to automatically configuring complex medical devices (e.g., an entire leg prosthesis) having a plurality (subset) of individual components. (See, for example, col. 1, line 65-col. 2, line 2 of Clynch where it is explained that Clynch is directed to a method of producing a more simplistic prosthetic or orthotic structure or device having a surface for engagement with the human body – e.g., a prosthetic socket). Thus, based on at least one patient attribute determined from the patient interview and/or other criteria, the system and method of the present invention can automatically sort through and select each of the plurality (subset) of individual components necessary to assemble the overall medical device. This is not the subject of Clynch and, therefore, is not taught or even suggested therein. As such, there are material differences between Clynch and the subject matter of the rejected claims. Consequently,

Applicant respectfully submits that Clynch cannot support a rejection of claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e).

Rejection of Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. (US 6,581,204). As Applicant does not believe Clynch in view of DeBusk et al. to teach the subject matter of claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81, the rejection is respectfully traversed.

The shortcomings of Clynch with respect to the present invention have been noted above. DeBusk et al. appears to be nothing more than an advanced medical supply inventory tracking and management system. DeBusk et al. does nothing to make up for the above documented deficiencies of Clynch and, in fact, the Examiner appears to cite DeBusk et al. only for its asserted disclosure of a component identification indicator. As such, Clynch in view of DeBusk et al. fails to teach or suggest at least:

a digital repository populated with entries defining medical *device* components, the entries each associated with an individual medical device component;

at least one patient attribute indicator associated with the entries;

a practitioner user interface mechanism configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one patient interview answer indicator;

a patient interview mechanism configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to store the at least one patient interview answer indicator in a memory, and

a configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient.

Consequently, in light of the significant deficiencies in the combined teachings of Clynch and DeBusk et al., Applicant respectfully submits that Clynch in view of DeBusk et al. cannot support a rejection of claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a).

Rejection of Claims 38 and 49 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 38 and 49 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of Vanker et al. (US 2002/0099631 A1). Applicant has amended independent claims 31 and 46 to more clearly describe the subject matter recited therein. As Applicant believes independent claims 31

and 46 to recite allowable subject matter as amended, claims 38 and 49, which respectively depend therefrom, would also be allowable.

Rejection of Claims 68 and 69 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 68 and 69 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of Haller et al. (US 2001/0051787 A1). Applicant has amended independent claim 65 to more clearly describe the subject matter recited therein. As Applicant believes independent claim 65 to recite allowable subject matter as amended, claims 68 and 69, which depend therefrom, would also be allowable.

Rejection of Claims 6 and 7 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. in further view of Vanker et al. Applicant has amended independent claim 1 to more clearly describe the subject matter recited therein. As Applicant believes independent claim 1 to recite allowable subject matter as amended, claims 6 and 7, which depend therefrom, would also be allowable.

Rejection of Claims 15, 17, 18 and 21 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 15, 17, 18 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. in further view of Haller et al. Applicant has amended independent claim 1 to more clearly

describe the subject matter recited therein. As Applicant believes independent claim 1 to recite allowable subject matter as amended, claims 15, 17, 18 and 21, which depend therefrom, would also be allowable.

CONCLUSION

Claims 1-39, 46-49, 65-69 and 80-82 remain pending in the present application. Applicant has amended claims 1, 31, 46 and 65 to more clearly describe the subject matter recited therein, and has also distinguished the subject matter of the present invention over the teachings of the references cited as prior art by the Examiner.

Therefore, Applicant respectfully submits that the present application is now in condition for allowance, and such action is earnestly requested. Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

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